

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

AMERICAN COLLEGE OF
OBSTETRICIANS AND
GYNECOLOGISTS, *et al.*,

Plaintiffs,

vs.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

Case No. 8:20-cv-1320-TDC

DEFENDANTS' SUPPLEMENTAL BRIEF IN OPPOSITION TO
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

The Supreme Court’s recent decision in *June Medical Services, LLC v. Russo*, No. 18-1323, 2020 WL 3492640 (U.S. June 29, 2020), confirms that Plaintiffs must, at a minimum, show that the Mifeprex in-person dispensing requirement is a substantial obstacle to a large fraction of women seeking an abortion in order to succeed on their due process claim. As Defendants have explained, Plaintiffs have failed to do so. *See* Defs.’ Opp. to Pls.’ Mot. for Prel. Inj. (“Defs.’ Opp.”) at 15-19. *June Medical* also does not alter the Plaintiff-providers’ lack of third-party standing, as Plaintiffs do not allege any governmental sanction for non-compliance with the in-person dispensing requirement and fail to show why they, rather than their patients, are the obvious claimants here.

I. *June Medical* Reaffirmed *Casey*’s Substantial-Obstacle Test.

Under *Casey*, Plaintiffs must, at a minimum, establish that the Mifeprex in-person dispensing requirement imposes a “substantial obstacle” to obtaining an abortion “in a large fraction of the cases in which [the requirement] is relevant.” *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 895 (1992) (joint op.); *see also Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016). As Defendants have explained, *see* Defs.’ Opp. at 14, in asking this Court to preliminarily enjoin the Mifeprex in-person dispensing requirement, Plaintiffs essentially ignore *Casey*’s substantial-obstacle test and instead seek to apply a free-floating cost-benefit analysis, *see* Pls.’ Mem. in Supp. of Mot. for Prel. Inj. at 24-28. But all nine Justices in *June Medical* emphasized the importance of demonstrating that a law poses a substantial obstacle to abortion access in order to obtain relief, *see June Medical*, 2020 WL 3492640, at *4, *7, *10, *12, *20 (plurality op.) (analyzing whether Louisiana law posed a substantial obstacle to abortion access); *id.* at *23-26 (Roberts, C.J., concurring in the judgment) (same); *id.* at *38-39 (Alito, J., joined by Thomas, Gorsuch, and Kavanaugh, JJ., dissenting) (same), and at least five Justices (a majority of the Court) explicitly *rejected* the sort of free-floating cost-benefit test that

Plaintiffs advocate, *see id.* at *23-26 (Roberts, C.J., concurring in the judgment); *id.* at *38-39 (Alito, J., joined by Thomas, Gorsuch, and Kavanaugh, JJ., dissenting); *id.* at *63 (Kavanaugh, J., dissenting).

As the Chief Justice’s controlling opinion in *June Medical* explained,¹ “[t]he opinion in *Whole Woman’s Health* began by saying” it was applying the framework set out in *Casey*, and “[n]othing about *Casey* suggested that a weighing of costs and benefits of an abortion regulation was a job for courts.” *Id.* at *24, *26 (Roberts, C.J., concurring in the judgment). “*Casey* instead focuses on the existence of a substantial obstacle, the sort of inquiry familiar to judges across a variety of contexts.” *Id.* at *24. In order to respect “the statement in *Whole Woman’s Health* that it was applying the undue burden standard of *Casey*,” therefore, the Chief Justice explained that courts must “requir[e] a substantial obstacle before striking down an abortion regulation.” *Id.* at *26. Thus, to establish a likelihood of success on their due process claim, Plaintiffs must at a minimum show that the Mifeprex in-person dispensing requirement poses a substantial obstacle to a large fraction of women seeking an abortion. Plaintiffs have failed to meet this standard. *See* Defs.’ Opp. at 15-19.

¹ As the narrowest position supporting the Court’s judgment, the Chief Justice’s concurrence in *June Medical* is the controlling opinion of the Court with respect to whether establishing a substantial obstacle is a prerequisite to obtaining relief. *See Marks v. United States*, 430 U.S. 188, 193 (1977); *see also June Medical*, 2020 WL 3492640, at *23 n.1 (Roberts, C.J., concurring in the judgment) (describing *Casey*’s plurality opinion as the holding of the Court because it was the narrowest opinion supporting the judgment). Under the Chief Justice’s opinion, a regulation that does not create a substantial obstacle to obtaining an abortion does not violate the Constitution.

II. *June Medical* Does Not Alter the Conclusion that Plaintiffs Have Failed to Show That the In-Person Dispensing Requirement Poses a Substantial Obstacle to a Large Fraction of Women Seeking an Abortion.

For the same reasons that Plaintiffs’ reliance on *Whole Woman’s Health* is misplaced, *see* Defs.’ Opp. at 24-25, any potential reliance Plaintiffs place on *June Medical* is likewise misplaced. In *June Medical*, the district court found that the Louisiana law would “restrict access to abortion in just the same way as Texas’s law, to the same degree or worse.” *June Medical*, 2020 WL 3492640, at *27 (Roberts, C.J., concurring in the judgment). In particular, the Texas law in *Whole Woman’s Health* would have reduced the number of abortion facilities in the state by half, while the Louisiana law in *June Medical* would have “reduce[d] ‘the number of clinics to one, or at most two,’ and the number of physicians in Louisiana to ‘one, or at most two,’” *id.* at *27, and—according to the plurality opinion—would have left “thousands of Louisiana women with no practical means of obtaining a safe, legal abortion,” *id.* at *19 (plurality op.). In this case, by contrast, there is *no* evidence that the in-person dispensing requirement has caused, or would cause, a comparably drastic reduction in the number of Mifeprex prescribers. Nor is there evidence that the requirement has forced, or would force, patients to undergo a more invasive abortion procedure, much less forgo an abortion altogether. *See* Defs.’ Opp. at 19-21.

As Defendants have explained, any slight increase in risk of exposure to COVID-19 associated with a one-time visit to a doctor’s office is at most an “incidental effect” of the in-person dispensing requirement and does not amount to a substantial obstacle. *See* Defs.’ Opp. at 16. Indeed, the same or similar “risk” of exposure to COVID-19 arises *whenever* a patient travels outside the home, whether to go to the store, the park, or any other location. CDC guidelines provide numerous steps patients and medical professionals can take to mitigate patient safety concerns in light of COVID-19. *See* Defs.’ Opp. at 16-17. Plaintiffs have not shown that

the risk of exposure to COVID-19, or any other incidental travel or expense associated with a one-time visit to a doctor's office, is a substantial obstacle to a large fraction of women seeking abortion.

III. Unlike the Admitting-Privileges Law in *June Medical*, the In-Person Dispensing Requirement Is Necessary to Ensure Patient Safety.

Because plaintiffs are unlikely to establish that the in-person dispensing requirement constitutes a substantial obstacle to a large fraction of patients seeking an abortion, the Court need consider the benefits of the requirement only in determining whether FDA has a “rational basis” to impose the requirement “in furtherance of its legitimate interests” in ensuring patient safety. *Gonzalez v. Carhart*, 550 U.S. 124, 158 (2007); see *June Medical*, 2020 WL 3492640, at *25 (Roberts, C.J., concurring in the judgment). The in-person dispensing requirement easily satisfies this lenient standard. See Defs.’ Opp. at 26-30.

In both *Whole Woman’s Health* and *June Medical*, the district courts concluded that the admitting-privileges laws failed to advance the states’ asserted interests in promoting women’s health and safety. See *June Medical*, 2020 WL 3492640, at *4, *6-7, *19-20 (plurality op.); *id.* at *27-28 (Roberts, C.J., concurring in the judgment). According to those district courts, the requirements to obtain admitting privileges at a hospital had “nothing to do with ability to perform medical procedures,” and abortion providers were unlikely to have the number of patients requiring hospitalization necessary to obtain or maintain such privileges. *Id.* at *27-28 (Roberts, C.J., concurring in the judgment) (internal quotation marks omitted).

Here, by contrast, FDA has determined that the in-person dispensing requirement is necessary to mitigate serious risks associated with use of Mifeprex—a determination that Congress entrusted squarely to FDA’s special expertise and which FDA based on multiple clinical trials and agency reviews. See Defs.’ Opp. at 22. The requirement ensures that: (1) at

the time of dispensing, the patient has the opportunity to receive counseling about the risk of serious patient complications associated with Mifeprex and what to do should they arise; and (2) the patient does not delay picking up the prescription—or the prescription is not delayed in the mail—before initiating an abortion, which could increase risks of serious bleeding or infection that might require surgical intervention. *See* Defs.’ Opp. at 24. Dispensing the drug in alternative settings, such as through retail or mail-order pharmacies, could expose patients to unnecessary and increased risks resulting from delays. *See* Defs.’ Opp. at 22-23. Thus, FDA has maintained the in-person dispensing requirement since it first approved Mifeprex in 2000. The in-person dispensing requirement is therefore rationally related to FDA’s interest in ensuring patient safety.

IV. The Plaintiff-Prescribers Continue to Lack Third-Party Standing Following *June Medical*.

June Medical likewise does not alter the conclusion that plaintiffs lack third-party standing. Unlike this case, the plurality in *June Medical* concluded that the defendant waived its standing argument. *June Medical*, 2020 WL 3492640, at *8-9 (plurality op.). Aside from this fact, the plurality opinion also stated that the plaintiffs had third-party standing based on the “threatened imposition of governmental sanctions for noncompliance” with the challenged statute, and because the abortion providers in that case were “far better positioned than their patients to address the burdens of compliance.” *Id.* at *10; *see also id.* at *26 n.4 (Roberts, C.J., concurring in the judgment). Neither of those features is present here. Plaintiffs do not allege that they would face any direct governmental sanctions for any conduct they wish to engage in. And the alleged burden in this case does not come from a regulation of physicians that patients are unlikely to know about; to the contrary, the alleged burden exists only because patients are told that they must visit a healthcare setting in person to obtain Mifeprex. Thus, unlike in *June*

Medical, Plaintiffs provide no reason why they, rather than their patients, are the “obvious claimant[s]” and the “least awkward challenger[s] . . . upon whom the challenged” in-person dispensing requirement “imposes legal duties and disabilities.” *Id.* at *9 (plurality op.) (internal quotation marks omitted). Nor have Plaintiffs established a sufficiently close relationship with hypothetical future patients to assert those patients’ rights; indeed, the whole object of this suit is to avoid the need for Plaintiffs to *ever* meet face-to-face with those hypothetical patients. *See* Defs.’ Opp. at 9-10.

CONCLUSION

For the reasons discussed above and in Defendants’ prior briefing, the Court should deny Plaintiffs’ motion for a preliminary injunction. At a minimum, any injunction should be no broader than necessary to redress any concrete, cognizable injuries actually established by Plaintiffs.

Dated: July 1, 2020

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CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of July 2020, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Hilary K. Perkins
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